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09/926,697	04/05/2002	Akane Takemura	011633	3246	
23850 7590 03/02/2010 KRATZ, QUINTOS & HANSON, LLP			EXAM	EXAMINER	
1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005			PORTER, RACHEL L		
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## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Application No. Applicant(s) 09/926,697 TAKEMURA ET AL. Office Action Summary Examiner Art Unit RACHEL L. PORTER 3626 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 07 December 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 47 and 52-54 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 47.52-54 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. \_\_ are subject to restriction and/or election requirement. 8) Claim(s) \_\_\_\_ Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some \* c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/SE/00)

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

#### Notice to Applicant

 This communication is in response to the amendment filed 12/7/09. Claims 47, 52-54 are pending.

#### Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- Claims 47, and 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 currently recites an "the display screen comprising an oral disease risk improvement *surface* further comprising a risk estimation part and a risk avoidance measure presentation part."

As described in the on page 18, lines 8-21 of the specification, the risk improvement table is described in a plurality of embodiments, including a *table display* realized using a computer program.

However, if applicants intends to claim merely a "display," (i.e. a screen displaying various parts), is unclear how portions of a page or any display item alone can function in the recited capacities (risk estimation, judgement, avoidance measure, improvement possibility). It is noted that the claim has been amended. However, the claim amendment fails to clarify the claim issues, as the current claim language still

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seems to emphasize the display or a form on a surface (in this case a computer screen).

The language of claim 53 underscores the lack of clarity in claim 47. Claim 53 recites "[t]he risk care business system as recited in claim 47, wherein the processing is performed according to a program stored on a non-transitory storage medium." The language of claim 53 suggests that while the the system of claim 47 recites a computer, input device, display comprising an output device, and the computer control processing information to control the display screen, there is no program or system component for processing of information in the recited fields. In other words, the recited system of claim 47 (and claim 53) merely displays a form on a computer screen. Furthermore, it is unclear which statutory class applicant is seeking to protect: the system; an article of manufacture (computer readable medium); or the method/ process.

Claims 52-54 inherit the deficiencies of claim 47 through dependency and are therefore also rejected.

## Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. Application/Control Number: 09/926,697 Page 4

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 Claims 47, 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summerell et al (US US 5937387A) in view of Iliff (US 6482156 B2)
 [claim 47] Summerell discloses a risk care business system, comprising:

- a computer, the computer processing information to control the display screen, (Col.
   7, lines 48-64, computer with processor)
- an information providing part comprising an input device, (col. 8, lines 8-29-computer includes peripherals, with input/ouput devices, display, printer keyboard)
- and a display screen comprising an output device, (col. 8, lines 8-29-computer includes peripherals, with input/ouput devices, display, printer keyboard)
- the display screen comprising a risk improvement surface further comprising a risk estimation part and a risk avoidance measure presentation part: (col. 8, lines 45-col. 9, line 25—risk estimation includes personal profile of user including health questionnaire; col. 16, lines 39-67 --risk avoidance suggestions on entering the program and how one can improve risks)
  - (a) wherein said risk estimation part includes:
    - a data gathering part that displays a current presence/absence of a plurality
      of risk factors and an answers section corresponding to the risk factors; (Fig.
      4-6; 15, col. 9, lines 15-61--questions regarding health and lifestyle risk
      factors)
    - a judgement criteria part that stipulates an unequivocal correlation between the answers and preset risk values; (col. 10, lines 51-67: Stratification rules are the mechanism used to determine which group and associated relative

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risk, fits the person's characteristics. Stratification rules use personal profile characteristic information which is calculated from the health profile questionnaire process.)

- a risk judgement part provided with a judgement section for recording the risk values for the risk factors converted from the answers of the answers section and space for calculating an overall risk value by arithmetic; and (Figure 14; col. 11, lines 36-38: Upon completing or updating the personal profile questionnaire, a graph depicting the user's physiological age is presented to the user 312.; col. 11, lines 44-49: FIG. 7 sets forth the steps required to determine an individual's physiological age. This requires calculating standard model properties 802, calculating composite relative risk 804, calculating survival for the user's composite relative risk 806, and calculating the user's physiological age 808)
- an overall risk display part provided with an overall risk judgement criteria
  section that unequivocally stipulates an overall risk allocated to one of a
  plurality of preset levels from the overall risk value, an overall risk display
  section that displays an overall risk showing a risk level of an examinee, and
  an explanation section that explains the risk level, and (Figure 15—
  physiological age, accounting for all risk factors in the personal profile and
  health questionnaire; Figures 18-19: physiological age and calendar age are
  represented along with risk factors and the alterations they make to one's
  physiological age)

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(b) wherein said risk avoidance measure presentation part includes

- a risk avoidance measure display part in which are shown a necessity of reexamination and a time of re-examination; (Fig. 22—discloses physiological age vs. calendar age at various time points (90-days, long-term)
- a guidance display section in wlaich are displayed guidance contents for
  guiding lifestyle habits so as to reduce the risk, and a tools display section in
  which are displayed tools effective for carrying out the risk improvement in
  accordance with a guidance of said guidance display section; and (figs. 2326—makes suggestions to user for improving health and reducing
  physiological age)
- an improvement possibility display part. (Figures 22-26-discloses how each
  change can reduce physiological age (max. years reduced if wellness strategy
  is followed, how risks can be changed)

Regarding the description of the risk improvement sheet as an "oral disease" risk improvement sheet and the description of the segments of the risk improvement sheet, Summerell does not expressly disclose that the health assessment system is used to assess one's risk of oral disease.

lliff discloses a health system which also screens for oral diseases, among health conditions in patients (col. 48, lines 25-31). At the time of the Applicant's invention, it would have been obvious one of ordinary skill in the art to modify the system of Summerell to include oral diseases among the types of diseases and risk factors

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assessed. As suggested by lliff, one would have been motivated to include this feature to provide patients with valuable information and advice, while the accounting for the various probabilities and scenarios the must be considered given a patient's full medical history. (col. 41, lines 24-56; col. 48, lines 25-31)

Furthermore, it should be noted that the type of risk improvement sheet (e.g. oral disease) is a description of the intended use of the system. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

[Claim 52] Summerell discloses a disease risk improvement system recited in claim 47 as explained in the rejection of claim 47, further comprising

- examination means for implementing a question-based examination as indicated
  by said risk improvement table on each test subject; (Col. 7, lines 48-64,
  computer with processor; col. 8, lines 8-29—input/output; col. 9, lines 15-30—
  questionnaire: all are means for implementation a question-based examination.)
- calculating means for applying examination results to the risk estimation part of said risk improvement table, working out a risk value for each risk factor judged objectively, and calculating an overall risk value; and (col. 10, lines 51-67:

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Stratification rules are the mechanism used to determine which group and associated relative risk, fits the person's characteristics. Stratification rules use personal profile characteristic information which is calculated from the health profile questionnaire process; Figure 14; col. 11, lines 36-38: Upon completing or updating the personal profile questionnaire, a graph depicting the user's physiological age is presented to the user 312.; col. 11, lines 44-49: FIG. 7 sets forth the steps required to determine an individual's physiological age. This requires calculating standard model properties 802, calculating composite relative risk 804, calculating survival for the user's composite relative risk 806, and calculating the user's physiological age 808)

Summerell discloses a system as explained in the rejection of claim 52, a further including means for implementing a question-based examination. However, Summerell does not expressly disclose an examination means for implementing an oral cavity examination.

Iliff discloses a health system which also screens for oral diseases, among health conditions in patients (col. 48, lines 25-31) (i.e. means for implementing oral cavity examination). At the time of the Applicant's invention, it would have been obvious one of ordinary skill in the art to modify the system of Summerell to include oral diseases among the types of diseases and risk factors assessed. As suggested by lliff, one would have been motivated to include this feature to provide patients with valuable information and advice, while the accounting for the various probabilities and scenarios

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the must be considered given a patient's full medical history. (col. 41, lines 24-56; col.

48, lines 25-31)

[Claim 53] Summerell discloses the risk care business system as recited in claim 47,

wherein the processing is performed according to a program stored on a non-transitory

storage medium. (col. 8, lines 16-24—computer includes means to store and run

instructions, logic to manipulate data)

[Claim 54] Summerell discloses The risk care business system as recited in claim 47,

wherein the computer is coupled to a host second computer coupled to the explanation

section and the guidance display section. (col. 7, lines 48-col. 8, line 29—includes client

server embodiment with connection to presentation/display means (i.e.  $% \left\{ 1\right\} =\left\{ 1$ 

explanation/guidance section))

Response to Arguments

6. Applicant's arguments with respect to claims 47, 52-54 have been considered but

are moot in view of the new ground(s) of rejection.

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#### Conclusion

- 7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Joao discloses a method and system for assessing the psychological health of individuals (US 5961332A); Iliff discloses a system and method for assessing and diagnosis patients (US 2008/0052123A1)
- Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 10-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./ Examiner, Art Unit 3626

/Robert Morgan/ Primary Examiner, Art Unit 3626